

## **REMARKS**

### **The Amendments**

Claims 1, 6 and 7 are amended in a merely formal manner. Claim 9 is amended to address and render moot the rejection under 35 U.S.C. §112, first paragraph.

It is submitted that the above amendments would put the application in condition for allowance. The amendment is believed to render moot the sole remaining ground of rejection. The amendments do not raise new issues or present new matter and do not present additional claims. The amendments have been made to direct the claims to the apparently allowable subject matter, which became evident after the Final action. Thus, they were not earlier presented. Accordingly, it is submitted that the requested amendments should be entered.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Rejection under 35 U.S.C. §112, first paragraph**

The rejection of claim 9 under 35 U.S.C. §112, first paragraph, is believed to be rendered moot by the above amendment. The recitation of treating type 1 diabetes, which gave rise to the rejection, is removed from the claim.

Although a moot issue, for completeness of the record, applicants have the following comments on the Januvia reference. This is a product insert which merely indicates that the specific DDPIV inhibitor called “Januvia” has not been approved for type 1 diabetes treatment.

It is not believed to support that there an absence of effect of this or other DPP IV inhibitors to treat type 1 diabetes. It cannot be concluded from the fact that approval is lacking that the drug has no activity for treating type 1 diabetes. There are many other reasons why a drug may not be approved for a particular use. For example, it is possible that approval simply has not been sought yet or that the approval process is not complete. Further, even if the absence of approval was due to efficacy issues, the level of efficacy needed for government approval to use does not evidence a lack of efficacy necessary for enablement. The standards are not the same. Thus, it is not believed that the Januvia reference provides evidence to support lack of enablement for the use of DPP IV inhibitors to treat type 1 diabetes.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,  
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